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EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,625

Applicant(s)

MCRURY ET AL.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 20-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 20-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 5, 7, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,488,690 to Morris et al. Regarding Claim 1, 7, and 20, Morris discloses a suture welding system [Column 2, lines 27-33] for fixedly attaching a first length of suture to a second length. Morris also discloses a method of using his welding system. Morris discloses an electrosurgical energy source [Column 3, lines 13-17: “power-supply”], a suture welding device (100) [see Fig. 1], a working end (distal end of device 100), and a suture contacting element (108). Morris discloses both unipolar and bipolar arrangements for his electrodes [Column 3, lines 10-13].

In his bipolar arrangement [Figure 1], he discloses a first electrode (first wire) electrically coupled to the power supply (a battery or other form of power) disposed on the contacting element (108) for providing electrical energy to the suture [Column 3, lines 10-29]. As a part of his bipolar configuration, Morris also discloses a second electrode (second wire) coupled to the battery, which provides a return energy path to the battery. Specifically, Morris describes a “pair of insulated wires” [Column 3, line 26]. Those of ordinary skill in the welding art know that a “bipolar” configuration

refers to an arrangement in which current travels from one electrode to another as a part of a complete circuit. Suture is put in the gap between the two electrodes and two lengths are attached to each other [Column 2, lines 38-48]. Figures 1 and 2 show the suture in contact with the suture contacting element (108). Although the respective locations of the tips of the wires are not clear from the disclosure, the *suture is certainly capable of being placed between them*. Figure 1 shows the suture between two grasping members and it can be assumed that one wire is in each grasper.

2. Regarding Claim 5, Morris discloses sutures that are thermoplastics such as nylon [Column 1, lines 26-30]. Such materials are “polymer plastics.”
3. Claims 20, 22-24, 25, 26, 29, and 31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,358,271 B1 to Egan et al. Regarding Claims 20 and 29, Egan discloses a method for attaching sutures (16 & 18) by providing electrical energy, a welding device (the whole machine), a working end (the distal end of the machine), and a suture contacting element (32). Egan discloses effecting the weld by various means, and although he mainly explains the ultrasonic embodiment, he also discloses employing “electrical arc discharge” to weld the sutures together [Column 3, lines 21-25; Column 6, lines 9-17]. Electrical arc discharge is when an electrical charge moves from one electrode through the air to another electrode. Electrical arc discharge, therefore, requires two electrodes. Egan

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does not specify which parts of his device would act as the electrodes, but assumedly it would be component (30) and another component.

4. Regarding Claims 22-24 and 31-33, Figures 15A and 15B show the two opposing (interior), which are movable relative to each other (Fig. 15B). The two sutures are shown in close contact and being constrained laterally by the two interior faces of members (32).
5. Regarding Claim 25, pods (32A) prevent the sutures from sliding out distally.
6. Regarding Claims 26 and 34, the sutures are made from polydioxanone [Column 6, line 8].

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 3, 4, and 28 are rejected under 35 U.S.C. 103 (a) as being anticipated by U.S. Patent No. 6,277,117 to Tetzlaff et al. in view of U.S. Patent No. 6,174,324 B1 to Egan et al. Regarding Claim 1, Tetzlaff discloses a welding device capable of welding suture having two electrodes (110/120), an energy source (“electrosurgical generator”) [Column 6, lines 31-33], and a suture contacting element [Column 1, lines 34-42]. His invention is intended for use in welding body tissue, but is certainly capable of welding *suture* as well. The working end is end of the device, which grips the material. He does not disclose first and second lengths of suture.

However, Egan teaches that instead of tying suture tips together to form a knot in a surgical procedure, applying thermal energy to melt the two suture tips together

provides some advantages [Column 1, lines 12-15; Column 2, lines 19-21]. Knots can be difficult to form in tight places, and different knots with various tensions can cause damage to the tissue. Conversely, *melting* the tips together with a machine such as Tetzlaff's would provide uniform tension in various knots and makes the procedure easier for the surgeon to perform. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use Tetzlaff's machine to melt two lengths of suture together, effecting a surgical closure, in order to close a wound effectively and more easily, *as taught by Egan*.

8. Regarding Claims 3 and 4, Tetzlaff discloses two opposing faces ("prongs") having a variable gap between them. Each face has an electrode (110/120) on top of it [Figure 2; Column 2, lines 41-48; Column 7, lines 49-58]. Although the stop member (106) [see Fig. 4 especially] prevents the electrodes from touching each other, *lengths of suture are capable of being placed between the two electrode surfaces and held there*.
9. Regarding Claim 28, the suture contacting element has pods (122) that the sutures could be tied onto, thus preventing them from sliding off.
10. Claims 1, 2, 8, and 27 are rejected under 35 U.S.C. 103(a) as being anticipated by U.S. Patent No. 5,342,359 to Rydell in view of U.S. Patent No. 6,174,324 B1 to Egan et al. Regarding Claim 1, Rydell discloses a system capable of welding suture having two electrodes (34/36) [Column 4, lines 65-66], an energy source ("energy source" – see Abstract), and a suture contacting element (distal end of device). His invention is

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intended for use in welding body tissue, but is certainly capable of welding suture as well. Rydell discloses a “bipolar” instrument, which means that one of the electrodes will provide electrical current and the other will provide for return of the current to the source when the two electrodes come in contact with each other. He does not disclose first and second lengths of suture.

However, Egan ‘324 teaches that instead of tying suture tips together to form a knot in a surgical procedure, applying thermal energy to melt the two suture tips together provides some advantages [Column 1, lines 12-15; Column 2, lines 19-21]. Knots can be difficult to form in tight places, and different knots with various tensions can cause damage to the tissue. Conversely, melting the tips together with a machine such as Tetzlaff’s would provide uniform tension in various knots and makes the procedure easier for the surgeon to perform. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use Tetzlaff’s machine to melt two lengths of suture together, effecting a surgical closure, in order to close a wound effectively and more easily, as taught by Egan ‘324.

11. Regarding Claim 2, Rydell’s device uses radio frequency waves [Column 8, lines 1-10; Column 5, lines 58-60].
12. Regarding Claim 8, with reference to Figure 4B, Rydell’s device has a piston (16) that slides and is able to engage suture positioned in the distal hollow of component 34. The piston slides from the position shown in Fig. 4A to the position shown in Fig. 4B [Column 5, lines 24-27]. The suture welding site is the whole hollow space inside member (34) and distal to piston (16).

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13. Regarding Claim 27, Rydell discloses a suture contacting element, which is the hollow interior surface of element (34).
14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,488,690 to Morris in view of U.S. Patent No. 4,052,988 to Doddi et al. Morris does not disclose making suture out of polydioxanone, but Doddi teaches that one ought to make suture for use in the body out of polydioxanone because it has many desirable properties, including strength, smoothness, and pliability. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make Morris' suture out of polydioxanone because this material has many surgically desirable properties such as tensile strength and pliability, as taught by Doddi.
15. Claims 21 and 30 rejected under 35 U.S.C. 103(a) as being anticipated by U.S. Patent No. 6,358,271 B1 to Egan et al. in view of U.S. Patent No. 5,342,359 to Rydell. Egan does not disclose radio frequency waves as an energy source, but this is a well known alternative energy source to ultrasonic and electric arc discharge, as demonstrated by Column 1, lines 12-18 of U.S. Patent No. 5,342,359 to Rydell. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use RF energy instead of electric arc discharge, as it is an alternate and analogous means of applying energy in surgical applications.

Response to Arguments

16. Applicant's arguments filed March 3, 2005 have been fully considered but they are not persuasive. First of all, regarding the phrase, "welding a first length of suture to a separate second length of suture," Examiner must interpret claims in their broadest reasonable sense: One portion of a suture is considered to be "separate" from another portion of *that same suture*. For example, when tying one's shoe lace, one holds *one length* of the lace in one's left hand and *another length* in one's right hand, and thereby ties a knot with them. The two lengths, although part of the same lace, are separated by the horizontal distance between them. The cited prior art references all read on this limitation.

A caveat: nowhere in the original specification does Applicant set forth welding two different sutures together, but always "a first length and a second length."

Claiming the welding of two different sutures together would constitute new matter.

17. Regarding Applicant's contention that "*Morris does not utilize electrosurgical energy*" (italics original), Examiner disagrees. Examiner interprets the word "electrosurgical" to mean electric energy used in a surgical setting. Morris' procedure is surely in the surgical setting, and electric energy is merely the flow of electrons through a conductor. In Column 2, lines 44-47, Morris clearly conveys that his device has "electrical conductors," a "battery," and that the tip of the tool may be "bipolar" to allow electricity to flow from one component to another. It is unclear to Examiner how Applicant does not construe Morris' procedure to employ "electrosurgical" energy.

18. Regarding the prior art reference U.S. Patent No. 6,358,271 to Egan, Examiner agrees that this reference discloses ultrasonic welding in one embodiment [see “REMARKS/ARGUMENTS, page 12, 4th paragraph], but maintains that this reference in an *alternative embodiment* also discloses using “various types of energy,” [column 3, lines 21-24] *including “electrical arc discharge,”* well known in art to be a process employing two electrodes. As explained above, the flow of electricity (as in electric arc discharge) in a surgical setting is considered to be “electrosurgical energy.”

Further regarding Egan, Examiner disagrees with Applicant’s argument that Egan does not disclose a suture element having “at least one pod” [see “REMARKS/ARGUMENTS, page 13, first two full paragraphs]. Merriam Webster Dictionary defines a pod (as used in the sense that Applicant uses) as “a usually protective container or housing.” The distal end (30A) of suture element (30), as shown in the embodiment of Fig. 14A very clearly has a smooth, hollowed out compartment for gripping and holding a suture therein, as described in column 9, lines 30-34.

19. Regarding Examiner’s rejection with Tetzlaff in view of Egan ‘324, as argued by Applicant in “REMARKS/ARGUMENTS, page 15 first full paragraph, Examiner maintains that if a surgeon had both devices on a table in front of him, and knew Egan’s teaching that melting/welding a suture knot is better than tying by hand [Egan ‘324, column 1 lines 12-15 and lines 39-44; column 2 lines 19-21], the surgeon would

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know to use Tetzlaff's device in order to melt two suture segments together to effect a "uniformly tensioned" suture knot.

20. Similarly, regarding Examiner's rejection with Rydell in view of Egan '324, as argued by Applicant in "REMARKS/ARGUMENTS, page 18, Examiner maintains that if a surgeon had both devices on a table in front of him, and knew Egan's teaching that melting/welding a suture knot is better than tying by hand [Egan '324, column 1 lines 12-15 and lines 39-44; column 2 lines 19-21], the surgeon would consider it obvious to use Rydell's device in order to melt two suture segments together to effect a "uniformly tensioned" suture knot. Examiner agrees that neither reference teaches such a configuration *by itself*: this is why Examiner made an obviousness rejection.

Examiner understands that human tissue and suture "are two vastly different materials with different welding concerns" ["REMARKS/ARGUMENTS, page 19, lines 27-28], however the *same principle* is at work in each case: welding, as defined by Merriam Webster Dictionary, is defined as:

to unite (metallic parts) by heating and allowing the metals to flow together or by hammering or compressing with or without previous heating
b : to unite (plastics) in a similar manner by heating.

Therefore, whether one is welding tissue or a suture, *in each case* one is raising the temperature of the molecules in order to melt them, causing the contiguous parts to adhere to each other. One of ordinary skill in the art of welding understand that various substances, *provided that they are capable of being melted*, are capable of

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being welded together by the application of an electric current. Both suture and tissue are capable of melting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
April 6, 2005


GLENN K. DAWSON
PRIMARY EXAMINER